

DEPARTMENT OF THE AIR FORCE 59TH MEDICAL WING (AETC) JOINT BASE SAN ANTONIO - LACKLAND TEXAS

3 MAR 2017

MEMORANDUM FOR SGVU

ATTN: JOSHUA CALCOTE

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

- 1. Your paper, entitled 59th Medical Wing Clinical Research Division Clinical Investigations Program Posters (Count: 16 of Varying Topics) presented at/published to Hanging in the Hallways at the 59th Medical Wing Clinical Research Division, Bldg 4430 in accordance with MDWI 41-108, has been approved and assigned local file #17110.
- 2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.
- 3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.
- 4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

LINDA STEEL-GOODWIN, Col, USAF, BSC Director, Clinical Investigations & Research Support

Linda Steel-Goodwin

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

INSTRUCTIONS

USE ONLY THE MOST CURRENT 59 MDW FORM 3039 LOCATED ON AF E-PUBLISHING

- 1. The author must complete page two of this form:
 - a. In Section 2, add the funding source for your study [e.g., 59 MDW CRD Graduate Health Sciences Education (GHSE) (SG5 O&M); SG5 R&D;
 Tri-Service Nursing Research Program (TSNRP); Defense Medical Research & Development Program (DMRDP); NIH; Congressionally Directed
 Medical Research Program (CDMRP); Grants; etc.1
 - b. In Section 2, there may be funding available for journal costs, if your department is not paying for figures, tables or photographs for your publication. Please state "YES" or "NO" in Section 2 of the form, if you need publication funding support.
- 2. Print your name, rank/grade, sign and date the form in the author's signature block or use an electronic signature.
- 3. Attach a copy of the 59 MDW IRB or IACUC approval letter for the research related study. If this is a technical publication/presentation, state the type (e.g. case report, QA/QI study, program evaluation study, informational report/briefing, etc.) in the "Protocol Title" box.
- 4. Attach a copy of your abstract, paper, poster and other supporting documentation.
- 5. Save and forward, via email, the processing form and all supporting documentation to your unit commander, program director or immediate supervisor for review/approval.
- 6. On page 2, have either your unit commander, program director or immediate supervisor:
 - a. Print their name, rank/grade, title; sign and date the form in the approving authority's signature block or use an electronic signature.
- 7. Submit your completed form and all supporting documentation to the CRD for processing (59crdpubspres@us.af.mil). This should be accomplished no later than 30 days before final clearance is required to publish/present your materials. If you have any questions or concerns, please contact the 59 CRD/Publications and Presentations Section at 292-7141 for assistance.
- 8. The 59 CRD/Publications and Presentations Section will route the request form to clinical investigations, 502 ISG/JAC (Ethics Review) and Public Affairs (59 MDW/PA) for review and then forward you a final letter of approval or disapproval.
- Once your manuscript, poster or presentation has been approved for a one-time public release, you may proceed with your publication or presentation submission activities, as stated on this form. Note: For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.
- 10. If your manuscript is accepted for scientific publication, please contact the 59 CRD/Publications and Presentations Section at 292-7141. This information is reported to the 59 MDW/CC. All medical research or technical information publications/presentations must be reported to the Defense Technical Information Center (DITC). See 59 MDWI 41-108, Presentation and Publication of Medical and Technical Papers, for additional information.
- 11. The Joint Ethics Regulation (JER) DoD 5500.07-R, Standards of Conduct, provides standards of ethical conduct for all DoD personnel and their interactions with other non-DoD entities, organizations, societies, conferences, etc. Part of the Form 3039 review and approval process includes a legal ethics review to address any potential conflicts related to DoD personnel participating in non-DoD sponsored conferences, professional meetings, publication/presentation disclosures to domestic and foreign audiences, DoD personnel accepting non-DoD contributions, awards, honoraria, gifts, etc. The specific circumstances for your presentation will determine whether a legal review is necessary. If you (as the author) or your supervisor check "NO" in block 17 of the Form 3039, your research or technical documents will not be forwarded to the 502 ISG/JAC legal office for an ethics review. To assist you in making this decision about whether to request a legal review, the following examples are provided as a guideline:

For presentations before professional societies and like organizations, the 59 MDW Public Affairs Office (PAO) will provide the needed review to ensure proper disclaimers are included and the subject matter of the presentation does not create any cause for DoD concern.

If the sponsor of a conference or meeting is a DoD entity, an ethics review of your presentation is not required, since the DoD entity is responsible to obtain all approvals for the event.

If the sponsor of a conference or meeting is a non-DoD commercial entity or an entity seeking to do business with the government, then your presentation should have an ethics review.

If your travel is being paid for (in whole or in part) by a non-Federal entity (someone other than the government), a legal ethics review is needed. These requests for legal review should come through the 59 MDW Gifts and Grants Office to 502 ISG/JAC.

If you are receiving an honorarium or payment for speaking, a legal ethics review is required.

If you (as the author) or your supervisor check "YES" in block 17 of the Form 3039, your research or technical documents will be forwarded simultaneously to the 502 ISG/JAC legal office and PAO for review to help reduce turn-around time. If you have any questions regarding legal reviews, please contact the legal office at (210) 671-5795/3365, DSN 473.

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement:

"The views expressed are those of the [author(s)] [presenter(s)] and do not reflect the official views or policy of the Department of Defense or its Components"

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving humans:

"The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402."

NOTE: All abstracts, papers, posters, etc., should contain the following disclaimer statement for research involving animals, as required by AFMAN 40-401 IP:

"The experiments reported herein were conducted according to the principles set forth in the National Institute of Health Publication No. 80-23, Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act of 1966, as amended."

PROCESSING OF PROFESSI	ONAL MEDICAL RI	ESEAR	RCH/TECHNICAL	PUBLICATI	ONS/PRE	SENTATIONS
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8. DO YOU NEED FUNDING SUPPORT FOR P	UBLICATION PURPOSE	ES:	YES NO			
9. IS THIS MATERIAL CLASSIFIED? YES	⊠ NO					
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Calcote, Joshua C joshua.c.calcote.ctr@i		,,	,		210-292	
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a. Primary/Corresponding Author						
Joshua C. Calcote	Contractor	59 M	DW/SGVU			
b.						
c.						
d.						
e.						
17. IS A 502 ISG/JAC ETHICS REVIEW REQU	JIRED (JER DOD 5500.0	07-R)? [YES NO		•	
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TO: Clinical Research Division	24. DATE RECEIVED		25. ASSIGNED PROCESSING REQUEST FILE NU	MBER
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27 Feb 2017				
28. AUTHOR CONTACTED FOR RECOMME		Y CHANGE	S: NO YES If yes, give date.	N/A
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59th Medical Wing Clinical Research Division

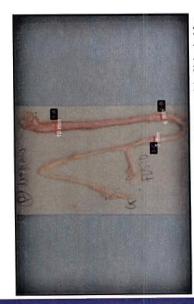
INICAL INVESTIGATIONS PROGRAM



Non-Human Research Subject Blood Donor Initiative" – PI: Linda Harris – Author: Erica Dean

The Non-Human Research Subject Blood Donor Initiative, designed by the CRD, resulted in a significant reduction in the number of animals required to support trauma-related protocols. Use of this protocol in other Clinical Investigations Facilities could drastically reduce

the number of animals required to support trauma- and resuscitation-focused research.



"Tissue Sharing from the Aortic Balloon Occlusion and the Abdominal Aortic and Junctional Tourniquet in a Coagulopathic Model of Pelvic Hemorrhage in Swine Study" – PJ: Matthew Wordsworth

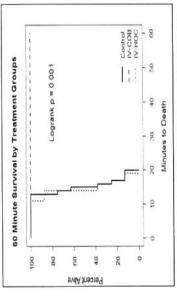
The purpose of this study is to map the nerve and better understand the anatomy of the swine before establishing and conducting future nerve studies (the nerve innervation may vary from strain to strain).

SUPPORTED RESEARCH



"Use of Miniature Marshmallows to Reduce Stress, Enhance Safety, and Increase Efficiency When Working With Sinciair Miniature Swine"

— PI: Linda Harris — Author: Erica Dean Sinclair Miniature Swine familiar with people and mini-marshmallows are easily trained to perform simple husbandry behaviors such as standing still or walking from one cage to another. These behaviors minimize the need for physical handling thereby reducing stress, decreasing procedure time, and enhancing safety.



"Efficacy of intravenous cobinamide versus hydroxocobalamin or saline for treatment of severe hydrogen sulfide toxicity in a swine (Sus Scorfa) model" – PI: Maj Joseph Maddry

Hydrogen sulfide (H₂S) is a potentially deadly gas that naturally occurs in petroleum and natural gas. This study compared the time to spontaneous ventilation among groups of same with acute H₂S-induced apared the time to spontaneous (UV) cobinamide, IV hydrox-coobalamin, or saline. All of the cobinamide-treated animals survived, whereas, none of the control or hydroxocobalamin-treated animals survived.



"The Frequency of Fungal Culture Contamination in Normal Toenalis versus Periodic Acid Schiff (PAS) and Gomori's Methenamine Silver (GMS) Stains in the Diagnosis of Onychomycosis" – Pl: Shannan McCann

Onychomycosis is a common worldwide problem identified in 14% of the population. This study used cultures and special stains of toenail clippings to determine if contamination of toenail samples (before collection) are being misinterpreted as Onychomycosis, if age relates to the level of contamination, and what are the organisms isolated in the clinically mormal toenails.



"Brain Magnetic Resonance Imaging (MRI) and Neuropathological Effects of Hypobaric Exposure to 30,000 Feet and Hyperoxemic Exposure at Sea Level in Miniature Swine" – PI: Col Paul Sherman

This study utilized miniature swine, a hypobaric chamber, and an MRI to safely and effectively demonstrate white matter injury (brain MRI changes) seen with high altitude (hypobaric) exposure in America's high altitude pilots and the observers who assist in the



LABORATORY BRANCH SUPPORT CAPABILITIES



Cell Biology & Immunology

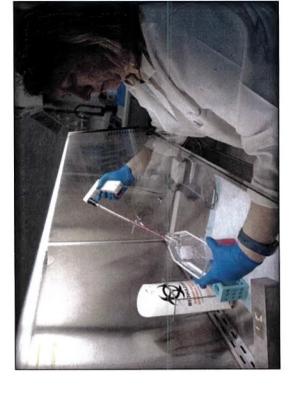
Equipment:

- Dedicated BSL-2 Hoods
- Flow Cytometer
- Fluorescent Microscopy
 - . Microdialysis Analysis Confocal Microscopy
- Microplate Reader

. Tissue Culture

- Proliferation-Viability
 - Cell Stain
- Fluorescent Microscopy/Image Analysis Analysis of Brain/Kidney Microdialysate
 - Single-Plex/Multiplex Biomarker Detection/Quantification
 - Cell Marker Detection/Identification









LABORATORY BRANCH SUPPORT CAPABILITIES



Microbiology

Equipment:

- VITEK Bacterial ID/Susceptibility System
 - Laminar Flow Biological Safety Cabinet Aerobic/Anaerobic Incubators

 - Bright Field Microscopy Electron Microscopy

- . Aerobic & Anaerobic Bacterial Cultures
 - . Bacterial ID and Susceptibility **Bacterial Adhesion Studies**
- Disinfectant Reliability Studies
 - **Epidemiology Studies**
- Comparison of Conventional & New Clinical Microbiology Methodologies









LABORATORY BRANCH SUPPORT CAPABILITIES



Molecular Biology

Next Generation Sequencers NextSeq 500

Personal Genome Machine (PGM)

Automated Extractor

PCR & RT-PCR

Pyro Sequencing

Sanger Sequencing

Fragment Analyzer Ultrasonicator

Microarray

. Nucleic Acid Sequencing . Full Genome

- Exome

Transcriptome

Multiplex-Targeted

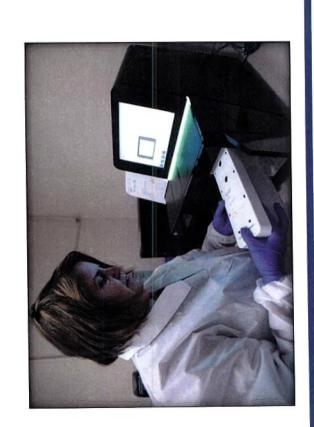
Genotyping/SNP Detection Microbiome

. Nucleic Acid Quantification and Quality Nucleic Acid Fragmentation

Assessment









LABORATORY BRANCH SUPPORT CAPABILITIES



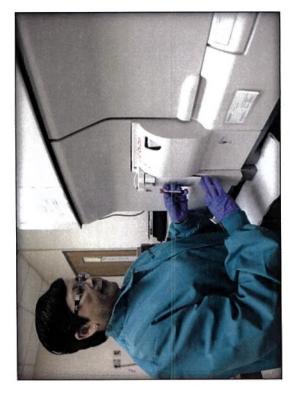
Hematology & Hemostasis

- . CBC Analyzer (Human & Multispecies Capa-
- Coagulation Analyzers
- Thromboelastograph Hemostasis Analyzers . STA-R Evolution Hemostasis System
 - ROTEM® Delta System
- . Complete Blood Count Capabilities:
- . Reticulocyte

. Platelet

- . Differential
- . Routine/Specialty Coagulation Testing . PT/PTT/Fibrinogen
- Clotting Time, Speed of Clot Formation, Clot









LABORATORY BRANCH SUPPORT CAPABILITIES



Chemistry / Toxicology

- High/Ultra Performance Liquid Chromatog-
- Photodiode Array Detectors
 - Fluorescent Detectors
- Clinical Chemistry Analyzer pH/ISE/Conductivity Meter
- Three-Liquid Chromatographic Triple Quadrupole Mass Spectrometers
 - Two-Gas Chromatographic Mass Specs
 - Solid Phase Extraction System

- . Drug and Drug Metabolites Natural Product Chemistry
- Disease Predictors
- Medical Readiness Research
- Full range of Clinical Chemistry analyses on
 - Therapeutic Drug/Immune Suppressants . High Sensitivity pH and Ion Monitoring Various Sample Types
 - Analgesics in Pain Management













SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

Methylation Status of Genes via Pyrosequencing

Supported Project:

Adverse childhood experience and serotonin transporters: a gene environmental interaction study of the risk of PTSD in soldiers (ACES)*

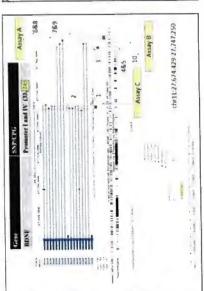
Principal Investigator: Capt Michael R. Hossack, MD

Dr. Jody Noe

Mr. Richard LaBoone Dr. Thomas Gibbons Mr. Leo Longoria

CRD Laboratory Support Staff:

CRD Support: GME investigators requested lab support to assess the methylation status of genes. After consulting with CRD Lab Scientist, Investigators decide to utilize Pyrosequencing for their Protocol.



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Dissemination:

- PCR Converted DNA

Verification of Assays

Selecting/Designing of Primers Selecting regions of Genome

A. Development:

. Collect & Extract DNA from Sample Bisulfite Conversion of DNA

B. Performance:

Pyrosequence

- Provide Data in Excel Format Analyze/Interpret Data
- Provide Materials & Methods for Publication of Research





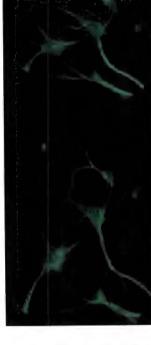
SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

Image Analysis via Laser Scanning Confocal Microscopy (LSCM)

Supported Projects:

"MYC and BCL-2 Double Immunohistochemistry on Diffuse large B Cell Lymphoma" - PI: Maj Jean Coviello CRD Laboratory Support Staff: Ms. Lori Henrichs, Ms. Sally Banfield, and Dr. Thomas Gibbons Expression of odorant receptors in non-olfactory neurons to induce selective axonal fasciculation* – PI: Maj Travis Newberry CRD Laboratory Support Staff: Ms. Patti Dixon and Dr. Thomas Gibbons CRD Support: GME investigators request lab support to assess chromosomal abnormalities via FISH, abnormal protein production via IHC, and directed nerve innervation in tissue culture.







A. Development:

- Coordinate with CRD Histology for FFPE
- Selecting FISH Probes
- Selecting Primary/Secondary Antibodies
- Optimization/Verification of Assays

B. Performance:

- Stain Samples

C. Dissemination:

- Deliver Stained Slides to PI
- Analyze/Interpret Data
- Provide Materials & Methods for Publication of Research





SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

"Saving the Unsurvivable with En Route Extracorporeal Membrane Oxygenation (ECMO)"

Principal Investigator: Maj Joseph Maddry, MD

Associate Investigators:

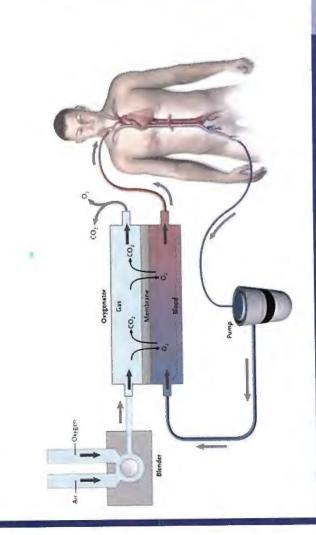
Capt James Lantry

Normalynn Garrett Shelia Savell, PhD, RN

Description:

This study will develop and provide an accelerated ECMO course to Military Critical Care Clinicians (MCCC) subjects and, subsequently, determine their ability to place ECMO intravascular catheters, initiate ECMO therapy in an ECMO patient, and troubleshoot common ECMO complications with and without teleconsultative support during transport of ECMO patients.

CRD Support: surgical suites; swine models; surgical technicians; pre/post-surgical care; animal housing; laboratory support









SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

"Evaluation of Prehospital Uncontrolled Hemorrhage and Use of Medical Adjunct Therapies"

Principal Investigator:

Associate Investigators:

Capt Kai Hata, MD

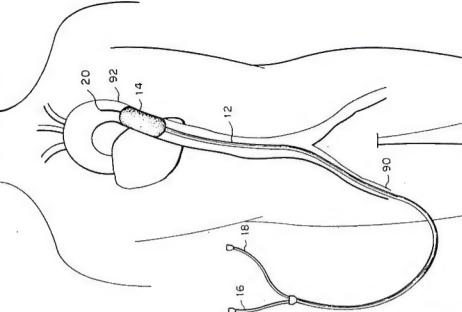
Problem: Hemorrhage is associated with greater than 90% of potentially survivable deaths on the battlefield. Survival from these injuries often leads to multiple organ failure and ischemic damage during evacuation to definitive medical care. Techniques for the control of hemorrhage and that protect patient vital organs during evacuation need to be improved.

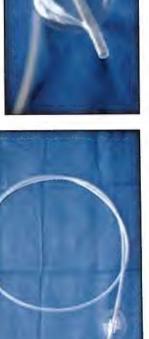
controlled hemorrhage and be used to induce suspended animation by profound hypothermia. New and advanced SAAP mechanical components, pumps, catheters, and oxygenators will be tested for This study is investigating if Selective Aortic Arch Perfusion (SAAP) can be used to treat both unCRD Support: surgical suites; swine models; surgical technicians; fresh whole blood; pre/post-

surgical care; animal housing; laboratory support













SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

"Comparison of the Efficacy of REBOA and AAJT in a Swine Model of Uncontrolled Pelvic Bleeding"

Principal Investigator:

Associate Investigators:

Jason Rall, PhD

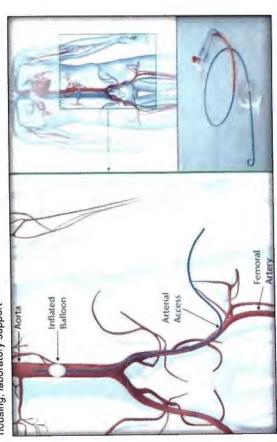
Ed Chagoy Jennifer Cox

Hypothesis

This study will test whether the Abdominal Aortic and Junctional Tourniquet (AAJT) will be as effective as Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) in achieving hemostasis in a swine model of pelvic hemorrhage and will determine the reperfusion injury produced by each treatment. AAJT application requires less time and skill than REBOA.

Military Relevance:

Hemorrhage due to injuries to the pelvis and junctional areas remains a difficult problem on the battlefield. Effective methodologies to stop hemorrhage from these areas are needed CRD Support: surgical suites; swine models; surgical technicians; pre/post-surgical care; animal housing; laboratory support











SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

"Brain Magnetic Resonance Imaging (MRI) and Neuropathological Effects of Hypobaric Exposure to 30,000ft and Hyperoxemic Exposure at Sea Level in a S*us scrofa domestica* model"

Principal Investigator: Col Paul Sherman, MD

Associate Investigators: Capt P. Dana Peralta, MD Lt Col John Sladky, MD Stephen McGuire, MD

ion:

In a continuing effort to demonstrate white matter injury seen with hypobaric exposure in our high altitude pilots and aerospace physiology altitude chamber inside-observers, 36 swine in 3 limbs were exposed to pre-determined altitude and O_2 levels 6 times over 3 weeks and underwent 3 MRI scans each. Unlike previous studies, these swine are non-sedated and alert during exposure. Serologic analysis and necropsy with neuropathological evaluation were performed on each animal.

This study utilized miniature swine, a hypobaric chamber, and an MRI to safely and effectively demonstrate white matter injury (brain MRI changes) seen with high altitude (hypobaric) exposure in America's high altitude pilots and the observers who assist in the aerospace physiology cham-

CRD Support: hypobaric chamber; specialized pre/post-flight animal cages; surgical suites; swine models; surgical technicians; pre/post-surgical care; pathology; laboratory support



















SPOTLIGHT ON GME/GHSE-SUPPORTED RESEARCH

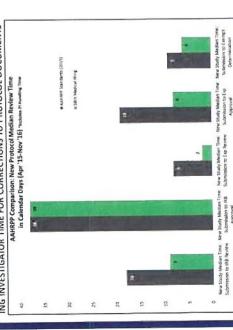
Calculating IRB Review & Approval Turn-Around Times

tracks the time it takes for Research Protocols to be reviewed and approved (i.e., turn-around time). The 59 MDW IRB developed a unique data mining system allowing for the pin-pointing of bottle-necks in the review process. IRB Records are examined for important milestone dates (e.g., protocol submission date, Notice of Action date, etc.) and these data are put into a spreadsheet where various turn-around times are cal-As part of the effort to earn national accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP), the 59th Medical Wing (59 MDW) Institutional Review Board (IRB) culated. All data entries correspond to color-coded study review types or IRB actions (see chart below). Such data collection enables highly specific IRB, Expedited, and Exempt review process improvements.

COLUMN HEADING SNAPSHOT OF TURN-AROUND TIME CALCULATION SPREADSHEET

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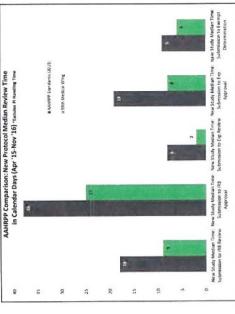


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INVESTIGATIONS PROGRAM 59th Medical Wing Clinical Research Division INICAL



A SNAPSHOT OF OUR HUMAN RESEARCH STUDIES

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